

Food and Drug Administration, HHS

§21.61

person to whom the record is subsequently disclosed together with, in the discretion of the Food and Drug Administration, a brief statement summarizing its reasons for refusing to amend the record. Any individual who includes false information in the statement of disagreement filed with the Food and Drug Administration may be subject to penalties under 18 U.S.C. 1001, the False Reports to the Government Act.

(4) That the individual has a right to seek judicial review of the refusal to amend the record.

(c) If the Commissioner on administrative appeal or a court on judicial review determines that the record should be amended in accordance with the individual's request, the Food and Drug Administration shall proceed in accordance with §21.51(d).

(d) A final determination on the individual's administrative appeal of the initial refusal to amend the record shall be concluded within 30 working days of the request for such review under paragraph (a) of this section, unless the Commissioner extends such period for good cause and informs the individual in writing of the reasons for the delay and of the approximate date on which a decision of the appeal can be expected.

[42 FR 15626, Mar. 22, 1977, as amended at 50 FR 52278, Dec. 23, 1985; 79 FR 68115, Nov. 14, 2014]

§21.53 Notation and disclosure of disputed records.

When an individual has filed a statement of disagreement under §21.52(b)(2), the Food and Drug Administration shall:

(a) Mark any portion of the record that is disputed to assure that the record will clearly show that portion is disputed whenever the record is disclosed.

(b) In any subsequent disclosure under §21.70 or §21.71(a), provide a copy of the statement of disagreement and, if the Food and Drug Administration deems it appropriate, a concise statement of the agency's reasons for not making the amendment(s) requested. While the individual shall have access to any such statement, it shall not be

subject to a request for amendment under §21.50.

(c) If an accounting was made under §21.71(d) and (e) of a disclosure of the record under §21.71(a), provide to all previous recipients of the record a copy of the statement of disagreement and the agency statement, if any.

§21.54 Amended or disputed records received from other agencies.

Whenever the Food and Drug Administration is notified that a record that it received from another agency was amended or is the subject of a statement of disagreement, the Food and Drug Administration shall:

(a) Discard the record, or clearly note the amendment or the fact of disagreement in its copy of the record, and

(b) Refer persons who subsequently request the record to the agency that provided it.

(c) If an accounting was made under §21.71 (d) and (e) of the disclosure of the record under §21.71(a), inform all previous recipients of the record about the amendment or provide to them the statement of disagreement and the agency statement, if any.

Subpart F—Exemptions

§21.60 Policy.

It is the policy of the Food and Drug Administration that record systems should be exempted from the Privacy Act only to the extent essential to the performance of law enforcement functions under the laws that are administered and enforced by the Food and Drug Administration or that govern the agency.

§21.61 Exempt systems.

(a) Investigatory records compiled for law enforcement purposes, including criminal law enforcement purposes, in the Food and Drug Administration Privacy Act Record Systems listed in paragraph (b) of this section are exempt from the following provisions of the Privacy Act (5 U.S.C. 552a) and of this part:

(1) Such records are exempt from 5 U.S.C. 552a(c)(3) and §21.71(e)(4), requiring that an individual be provided with the accounting of disclosures of records

§21.65

21 CFR Ch. I (4–1–16 Edition)

about himself from a Privacy Act Record System.

(2) Except where access is required under 5 U.S.C. 552a(k)(2) and §21.65(a)(2), (such records are exempt from 5 U.S.C. 552a(d)(1) through (4) and (f) and §§21.40 through 21.54, requiring procedures for an individual to be given notification of and access to records about himself in a Privacy Act Record System and to be allowed to challenge the accuracy, relevance, timeliness, and completeness of such records.

(3) Such records are exempt from 5 U.S.C. 552a(e)(4)(G) and (H) and §21.20(b)(1) requiring inclusion in the notice for the system of information about agency procedures for notification, access, and contest.

(4) Such records are exempt from 5 U.S.C. 552a(e)(3) requiring that individuals asked to supply information be provided a form outlining the authority for the request, the purposes for which the information will be used, the routine uses in the notice for the Privacy Act Record System, and the consequences to the individual of not providing the information, but only with respect to records compiled by the Food and Drug Administration in a criminal law enforcement investigation where the conduct of the investigation would be prejudiced by such procedures.

(b) Records in the following Food and Drug Administration Privacy Act Record Systems that concern individuals who are subject to Food and Drug Administration enforcement action and consist of investigatory records compiled for law enforcement purposes, including criminal law enforcement purposes, are exempt under 5 U.S.C. 552a(j)(2) and (k)(2) from the provisions enumerated in paragraph (a) of this section:

(1) Bio-research Monitoring Information System—HHS/FDA/09–10–0010.

(2) Regulated Industry Employee Enforcement Records—HHS/FDA/ACMO/09–10–002.

(3) Employee Conduct Investigative Records—HHS/FDA/ACMO/09–10–0013.

(c) The system described in paragraph (b)(3) of this section includes investigatory records compiled solely for the purpose of determining suitability, eligibility, or qualification for Federal

civilian employment, military service, Federal contracts, and access to classified information. These records are exempt from disclosure under 5 U.S.C. 552a(k)(5) to the extent that the disclosure would reveal the identity of a source who furnished information to the Government under a promise of confidentiality, which must be an express promise if the information was furnished after September 27, 1975. Any individual who is refused access to a record that would reveal a confidential source shall be advised in a general way that the record includes information that would reveal a confidential source.

(d) Records in the following Food and Drug Administration Privacy Act Records Systems are exempt under 5 U.S.C. 552a(k)(2) and (k)(5) from the provisions enumerated in paragraph (a)(1) through paragraph (a)(3) of this section: FDA Records Related to Research Misconduct Proceedings, HHS/FDA/OC, 09–10–0020.

[42 FR 15626, Mar. 22, 1977, as amended at 46 FR 8459, Jan. 27, 1981; 50 FR 52278, Dec. 23, 1985; 78 FR 39186, July 1, 2013]

§21.65 Access to records in exempt systems.

(a) Where a Privacy Act Record System is exempt and the requested records are unavailable under §21.61, an individual may nevertheless make a request under §21.40 for notification concerning whether any records about him exist and request access to such records where they are retrieved by his name or other personal identifier.

(b) An individual making a request under paragraph (a) of this section;

(1) May be given access to the records where available under part 20 of this chapter (the public information regulations) or the Commissioner may, in his discretion, entertain a request under any or all of the provisions of §§21.40 through 21.54; and

(2) Shall be given access upon request if the records requested are subject to 5 U.S.C. 552a(k)(2) and not to 5 U.S.C. 552a(j)(2) (i.e., because they consist of investigatory material compiled for law enforcement purposes other than criminal law enforcement purposes) and maintenance of the records resulted in denial to the individual of